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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/788,475

03/01/2004

Barry H. Ginsberg

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06/27/2007

ROYLANCE, ABRAMS, BERDO & GOODMAN, L.L.P.

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SUITE 600

WASHINGTON, DC 20036

EXAMINER

MALLARI, PATRICIA C

ART UNIT

PAPER NUMBER

3735

MAIL DATE

DELIVERY MODE

06/27/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/788,475

Applicant(s)

GINSBERG, BARRY H.

Examiner

Patricia C. Mallari

Art Unit

3735

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 09 April 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-62 is/are pending in the application.
- 4a) Of the above claim(s) 1-4, 10-19 and 28-40 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 41-51 is/are allowed.
- 6) ☒ Claim(s) 5-9, 20-27 and 52-62 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 May 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
- Paper No(s)/Mail Date 3/19/04.

- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Oath/Declaration***

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because it does not state that the person making the oath or declaration acknowledges the duty to disclose to the Office all information known to the person to be material to patentability as defined in 37 CFR 1.56. Instead, the declaration states that the person making the declaration acknowledges a duty to disclose "information which is material to the *examination* of this application" (emphasis added).

The declaration is further defective because the clause regarding "willful false statements ..." required by 37 CFR 1.68 has been omitted.

### ***Election/Restrictions***

Applicant's election with traverse of invention II in the reply filed on 4/9/07 is acknowledged. The traversal is on the ground(s) that it should not constitute a serious burden on the examiner to search and examine all of the claims identified as Inventions I and II. This is not found persuasive because different search strategies and queries are required for each of the inventions. Additionally, because some of the method may be practiced by hand, the prior art applicable to one invention (method) would not likely

be applicable to another invention (the apparatus). Finally, the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph. Because of the above reasons, there is an undue burden on the examiner to search both inventions.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-4, 10-19, and 28-40 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected group, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 4/9/07.

### ***Drawings***

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: reference numeral (66) in figure 2. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required

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corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### ***Claim Objections***

Claim 57 is objected to because of the following informalities:

Claim 57 recites "processing device is programmable to wherein the step of determining a carbohydrate to insulin ratio for the selected period comprises the step of" should be replaced with "wherein determining a carbohydrate to insulin ratio for the selected period comprises calculating". Appropriate correction is required.

Claims 58-62 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claims 58-62 recite, "An apparatus as claimed . . . , further comprising the step of determining". Since the invention claimed is an apparatus, rather than a method, the step(s) fail to further limit the parent claim because there is no connection or relationship set forth between the step and the apparatus. Also see the rejection under 35 U.S.C. 101 set forth below.

### ***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 58-62 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claims 58-62 are directed to an apparatus but further comprise a "step", wherein such a step is a component of a method or process, rather than an apparatus. These claims fall within multiple enumerated statutory categories rather than within one of the categories. Claims 55-57, which, like claims 58-62, also depend from claim 52, recite, "wherein the processing device is programmable to" execute a step. If the applicant were to amend the steps of claims 58-62 to language similar to that of claims 55-57, this rejection might be overcome. For example, "further comprising the step of determining" on lines 1-2 of claim 58 should be amended to read, "wherein the processing device is programmable to determine".

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 5-9, 20-27, and 52-62 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent Application Publication 2003/0028089 to Galley et al. Galley describes an apparatus for determining factors for insulin therapy comprising a memory device (see entire document especially paragraph 35 of Galley) and a processing device 14 (see entire document, especially paragraphs 33 and 34 of Galley).

As to the language “for determining factors for insulin therapy” in the preamble of claim 5 and “for storing at least one data set . . .” describing the memory device of claim 5, the applicants should note that this is merely “intended use” language, describing the intended use of the memory device, which cannot be relied upon to define over the prior art since the prior art teaches all of the claimed structural limitations and their recited relationships. See *Ex parte Masham* 2 USPQ2d 1647. The memory device of the prior art is certainly capable of storing any type of data, including the data set recited in claim 5. The applicants should further note that language in claims 20 and 52 similar to the language in claim 5 identified above is also considered “intended use” language and therefore is treated the same as discussed above.

The applicants should also note that claims 5-8, 20-27, and 52-62 merely state that the processing device be “programmable” to execute the steps described in each claim. Any processor, processing device, microprocessor, control unit, or controller is fully capable of being programmed to execute any steps, such as those delineated in claims 5-8, 20-27, and 52-62.

Regarding claim 9, the processing device may be a personal data assistant (see entire document, especially paragraph 34 of Galley).

Regarding claims 20-27 and 52-62, the processing device 14 is connected to the memory device (see entire document, especially paragraph 35 of Galley).

***Allowable Subject Matter***

Claims 41-51 are allowed.

The following is a statement of reasons for the indication of allowable subject matter:

The primary reason for the allowance of claims 41-51 is the inclusion of combination of the second set of instructions to calculate a delta blood glucose level corresponding to the difference between readings taken respectively, at substantially the beginning of and substantially the end of the selected period and the third set of instructions to determine a correct insulin amount using the delta blood glucose level divided by an insulin sensitivity factor. US Patent Application Publication No. 2003/0114836 to Estes et al. teaches a computer readable medium of instructions to determine factors used for insulin therapy comprising sets of instructions for determining a correct insulin amount using the delta blood glucose level divided by an insulin sensitivity factor. However, the delta blood glucose level of Estes corresponds to a difference between a current blood glucose level and a target blood glucose level rather than the difference between blood glucose levels at the beginning and end of the selected period (see entire document, especially paragraphs 47-49 of Estes).

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia C. Mallari whose telephone number is (571) 272-4729. The examiner can normally be reached on Monday-Friday 10:00 am-6:30 pm.



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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on (571) 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Patricia Mallari  
Patent Examiner  
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